July 9, 2025

GE Medical Systems Information Technologies, Inc.
Yanli Sun
Regulatory Affairs Manager
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K242562
Trade/Device Name: Monitor B105M; Monitor B125M; Monitor B155M; Monitor B105P; Monitor B125P
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DPZ, DQK, DSI, DSJ, DSK, GWQ, FLL, NHO, NHP, NHQ, KRB, MLD, OLT, OLW, OMC, ORT, KOI
Dated: August 28, 2024
Received: December 27, 2024

Dear Yanli Sun:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242562

Device Name
Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P

Indications for Use *(Describe)*
The monitor B105M, B125M, B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner.

The monitor B105M, B125M, B155M, B105P and B125P are not Apnea monitors (i.e., do not rely on the device for detection or alarm for the cessation of breathing). These devices should not be used for life sustaining/supporting purposes.

The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI.

The monitor B105M, B125M, B155M, B105P and B125P can be stand-alone monitors or interfaced to other devices via network.

The monitor B105M, B125M, B155M, B105P and B125P monitor and display: ECG (including ST segment, arrhythmia detection, ECG diagnostic analysis and measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/ Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/Surface temperature, impedance respiration, respiration rate, airway gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate), Cardiac Output (C.O.), Entropy, neuromuscular transmission (NMT) and Bispectral Index (BIS).

The monitor B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, “R on T”, Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1):

Date: July 9th, 2025

Submitter: GE Medical Systems *Information Technologies,* Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

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Device names (807.92(a)(2):

Trade Name: Monitor B105M, Monitor B125M, Monitor B155M, Monitor B105P, Monitor B125P

Common/Usual Name: Multiparameter patient monitor (monitor, physiological, patient (with arrhythmia detection or alarms)

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Classification Names:	21 C.F.R. §870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm). 21 C.F.R. §868.2375 Breathing frequency monitor. 21 C.F.R. §870.1110 Blood pressure computer. 21 C.F.R. §870.1130 Noninvasive blood pressure measurement system. 21 C.F.R. §870.2700 Oximeter 21 C.F.R. §870.2710 Ear oximeter. 21 C.F.R. §880.2910 Clinical electronic thermometer. 21 C.F.R. §882.1400 Electroencephalograph 21 C.F.R. §870.1100 alarm, blood-pressure 21 C.F.R. §870.1425 Programmable diagnostic computer. 21 C.F.R. §870.2300 Cardiac monitor (including cardiotachometer and rate alarm). 21 C.F.R. §868.1400 Carbon dioxide gas analyzer. 21 C.F.R. §868.1500 Enflurane gas analyzer. 21 C.F.R. §868.1500 Desflurane gas analyzer 21 C.F.R. §868.1500 Sevoflurane gas analyzer 21 C.F.R. §868.1500 Isoflurane gas analyzer 21 C.F.R. §868.1620 Halothane gas analyzer. 21 C.F.R. §868.1700 Nitrous oxide gas analyzer. 21 C.F.R. §868.1720 Oxygen gas analyzer. 21 C.F.R. §870.1915 Thermodilution probe. 21 C.F.R. §868.2775 Electrical peripheral nerve stimulator
Product Code:	MHX
Subsequent Product Code:	BZQ, CBR, CBS, CBQ, CCK, CCL, DXN, DQA, DRT, DPZ, DQK, DSI, DSJ, DSK, GWQ, FLL, NHO, NHP, NHQ, KRB, MLD, OLT, OLW, OMC, ORT, KOI
Predicate Device(s) (807.92(a)(3)):	Primary Predicate: K213490 Monitors B105M, B125M, B155M, B105P and B125P Additional Predicate Devices: CARESCAPE Monitor B450 (K213363)
Device Description (807.92(a)(4)):	The proposed monitors B105M, B125M, B155M, B105P and B125P are new version of multi-parameter patient monitors developed based on the predicate monitors B105M, B125M, B155M, B105P and B125P (K213490) to provide additional monitored parameter Bispectral Index (BIS) by supporting the additional optional E-BIS module (K052145) which used in conjunction with Covidien BISx module (K072286).

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In addition to the added parameter, the proposed monitors also offer below several enhancements:

- Provided data connection with GE HealthCare anesthesia devices to display the parameters measured from anesthesia devices (Applicable for B105M, B125M and B155M).
- Modified Early Warning Score calculation provided.
- Separated low priority alarms user configurable settings from the combined High/Medium/Low priority options.
- Provided additional customized notification tool to allow clinician to configure the specific notification condition of one or more physiological parameters measured by the monitor. (Applicable for B105M, B125M and B155M).
- Enhanced User Interface in Neuromuscular Transmission (NMT), Respiration Rate and alarm overview.
- Provided Venous Stasis to assist venous catheterization with NIBP cuff inflation.
- Supported alarm light brightness adjustment.
- Supported alarm audio pause by gesture (Not applicable for B105M and B105P).
- Supported automatic screen brightness adjustment.
- Supported network laser printing.
- Continuous improvements in cybersecurity

The proposed monitors B105M, B125M, B155M, B105P and B125P retain equivalent hardware design based on the predicate monitors and removal of the device Trim-knob to better support cleaning and disinfecting while maintaining the same primary function and operation.

Same as the predicate device, the five models (B105M, B125M, B155M, B105P and B125P) share the same hardware platform and software platform to support the data acquisition and algorithm modules. The differences between them are the LCD screen size and configuration options. There is no change from the predicate in the display size.

As with the predicate monitors B105M, B125M, B155M, B105P and B125P (K213490), the proposed monitors B105M, B125M, B155M, B105P and B125P are multi-parameter patient monitors, utilizing an LCD display and pre-configuration basic parameters: ECG, RESP, NIBP, IBP, TEMP, SpO2, and optional parameters which include CO2 and Gas parameters provided by the E-

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MiniC module (K052582), CARESCAPE Respiratory modules E-sCO and E-sCAiO (K171028), Airway Gas Option module N-CAiO (K151063), Entropy parameter provided by the E-Entropy module (K150298), Cardiac Output parameter provided by the E-COP module (K052976), Neuromuscular Transmission (NMT) parameter provided by E-NMT module (K051635) and thermal recorder B1X5-REC.

The proposed monitors B105M, B125M, B155M, B105P and B125P are not Apnea monitors (i.e., do not rely on the device for detection or alarm for the cessation of breathing). These devices should not be used for life sustaining/supporting purposes. Do not attempt to use these devices to detect sleep apnea.

As with the predicate monitors B105M, B125M, B155M, B105P and B125P (K213490), the proposed monitors B105M, B125M, B155M, B105P and B125P also can interface with a variety of existing central station systems via a cabled or wireless network which implemented with identical integrated WiFi module. (WiFi feature is disabled in B125P/B105P).

Moreover, same as the predicate monitors B105M, B125M, B155M, B105P and B125P (K213490), the proposed monitors B105M, B125M, B155M, B105P and B125P include features and subsystems that are optional or configurable, and it can be mounted in a variety of ways (e.g., shelf, countertop, table, wall, pole, or head/foot board) using existing mounting accessories.

Indications for Use (807.92(a)(5)):

The monitor B105M, B125M, B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner.

The monitor B105M, B125M, B155M, B105P and B125P are not Apnea monitors (i.e., do not rely on the device for detection or alarm for the cessation of breathing). These devices should not be used for life sustaining/supporting purposes.

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The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI.

The monitor B105M, B125M, B155M, B105P and B125P can be stand-alone monitors or interfaced to other devices via network.

The monitor B105M, B125M, B155M, B105P and B125P monitor and display: ECG (including ST segment, arrhythmia detection, ECG Diagnostic Analysis and Measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/ Core/Surface temperature, impedance respiration, respiration rate, airway Gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiratory rate), Cardiac output (C.O.), Entropy, neuromuscular transmission (NMT) and Bispectral Index (BIS).

The monitor B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, “R on T”, Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.

Contraindications for using the monitor
The monitors B105M, B125M, B155M, B105P and B125P are not intended for use during MRI.

Technology (807.92(a)(6)): The proposed monitors B105M, B125M, B155M, B105P and B125P are the new version of the devices (modular multi-parameter patient monitor).

It incorporates a new version of the software VSP 4.0. The new version VSP 4.0 software can be installed as an upgrade on the

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predicate monitors B105M, B125M, B155M, B105P and B125P (with software VSP 3.0) (K213490).

The hardware functionality is unchanged compared to the predicate Monitors (K213490), however this 510(k) introduces monitoring of additional (previously cleared) parameter through an existing cleared and marketed measurement module, removes device Trim-knob, enhancements of several software features and additional cybersecurity enhancements.

The fundamental technology of the proposed monitors B105M, B125M, B155M, B105P and B125P are same as the predicate devices.

The proposed monitors B105M, B125M, B155M, B105P and B125P are substantially equivalent to the predicate devices.

A summary of the main changes compared to the predicate are listed below in the comparison table.

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Product Comparison versus Predicate Main Features:

The proposed monitors B105M, B125M, B155M, B105P and B125P share equivalent indications for use, intended use patient populations, and functional features as the predicate devices. The proposed monitors B105M, B125M, B155M, B105P and B125P consist of improvements and optional features outlined below that are substantially equivalent to the predicate devices.

Specification	The legally marketed predicate monitors B105M/B125M/B155M/B105P/B125P with Software VSP 3.0 (K213490)	Proposed monitors B105M/B125M/B155M/B105P/B125P with Software VSP 4.0	Differences
• FDA Primary Product Code	MHX	MHX	**Identical**
• FDA Classification Regulation	21 CFR 870.1025	21 CFR 870.1025	**Identical**
• Indications for Use	The monitor B105M, B125M, B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport. The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner. The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI. The monitor B105M, B125M, B155M, B105P and B125P can be a stand-alone monitor or interfaced to other devices via network. The monitor B105M, B125M, B155M, B105P and B125P monitor and display: ECG (including ST segment, arrhythmia detection, ECG Diagnostic Analysis and Measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/ Nasopharyngeal/ Tympanic/ Rectal/ Bladder/ Axillary/ Skin/ Airway/ Room/ Myocardial/ Core/ Surface temperature, impedance respiration, respiration rate, airway Gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification	The monitor B105M, B125M, B155M, B105P and B125P are portable multi-parameter patient monitors intended to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport. The monitor B105M, B125M, B155M, B105P and B125P are intended for use under the direct supervision of a licensed health care practitioner. **The monitor B105M, B125M, B155M, B105P and B125P are not Apnea monitors (i.e., do not rely on the device for detection or alarm for the cessation of breathing). These devices should not be used for life sustaining/supporting purposes.** The monitor B105M, B125M, B155M, B105P and B125P are not intended for use during MRI. The monitor B105M, B125M, B155M, B105P and B125P can be a stand-alone monitor or interfaced to other devices via network. The monitor B105M, B125M, B155M, B105P and B125P monitor and display: ECG (including ST segment, arrhythmia detection, ECG Diagnostic Analysis and Measurement), invasive blood pressure, heart/pulse rate, oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), functional oxygen saturation (SpO2) and pulse rate via continuous monitoring (including monitoring during conditions of clinical patient motion or low perfusion), temperature with a reusable or disposable electronic thermometer for continual monitoring Esophageal/ Nasopharyngeal/ Tympanic/ Rectal/ Bladder/ Axillary/ Skin/ Airway/ Room/ Myocardial/ Core/ Surface temperature, impedance respiration, respiration rate, airway Gases (CO2, O2, N2O, anesthetic agents, anesthetic agent identification	**Equivalent to predicate**. Same features found in the predicate Monitor are retained, with the additional of Bispectral index (BIS) parameter measurement. The addition of the BIS measurement is supported through previously cleared E-BIS module (K052145) conjunction with and Covidien BISx module (K072286). The proposed device only displays the measurement result from E-BIS module (K052145) conjunction with Covidien BISx module (K072286). The proposed device adds claim that the proposed devices are not Apnea monitors. The changes do not significantly affect substantial equivalence.

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	and respiratory rate), Cardiac output (C.O.), Entropy and neuromuscular transmission (NMT). The monitor B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, "R on T", Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.	and respiratory rate), Cardiac output (C.O.), Entropy, Neuromuscular transmission (NMT) and **Bispectral Index (BIS).** The monitor B105M, B125M, B155M, B105P and B125P are able to detect and generate alarms for ECG arrhythmias: Asystole, Ventricular tachycardia, VT>2, Ventricular Bradycardia, Accelerated Ventricular Rhythm, Ventricular Couplet, Bigeminy, Trigeminy, "R on T", Tachycardia, Bradycardia, Pause, Atrial Fibrillation, Irregular, Multifocal PVCs, Missing Beat, SV Tachy, Premature Ventricular Contraction (PVC), Supra Ventricular Contraction (SVC) and Ventricular fibrillation.	
• Patient Population	Adult, pediatric and neonate	Adult, pediatric and neonate	**Identical**
• Use Environment	A professional healthcare facility	A professional healthcare facility	**Identical**
• Available Parameters	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, heart/pulse rate, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), Entropy, Cardiac Output, neuromuscular transmission (NMT).	ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, heart/pulse rate, non-invasive blood pressure, pulse oximetry, temperature, impedance respiration, airway gases (CO2, O2, N2O, and anesthetic agents), Entropy, Cardiac Output, neuromuscular transmission (NMT), **Bispectral Index (BIS**).	**Equivalent to predicate**. The BIS parameter has been added and can be displayed on the screen, through the compatibility/supported E-BIS module (K052145) conjunction with Covidien BISx module (K072286). This change solely adds the capability to display the BIS parameters on the proposed device's display, similar to the other displayed parameters. The changes do not significantly affect substantial equivalence.
• E-Modules	E-MiniC E-sCO E-sCAiO N-CAiO E-ENTROPY E-COP E-NMT	E-MiniC E-sCO E-sCAiO N-CAiO E-ENTROPY E-COP E-NMT **E-BIS**	**Equivalent to predicate.** Support added for additional parameter measurement module E-BIS module (K052145). The E-BIS module is cleared and available on the market. This change solely adds the capability to display these additional parameters on the proposed device's display, similar to the other displayed parameters. The changes do not significantly affect substantial equivalence.
• Maximum E-Modules Support	B105M, B125M, B155M: Maximum three E-Modules can be supported at the same time: One through module rack, two through external Second Frame B1X5-F2. B105P, B125P:	B105M, B125M, B155M: Maximum three E-Modules can be supported at the same time: One through module rack, two through external Second Frame B1X5-F2. B105P, B125P:	**Identical**

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	Maximum one E-Module can be supported through the module rack.	Maximum one E-Module can be supported through the module rack.	
• Respiration Rate Measurement Algorithm	GEHC Respiration Rate measurement algorithm	GEHC Respiration Rate measurement algorithm	**Identical**
• Peripheral Interfaces	Network interface: RJ-45 Mains input Module bus Connector Defibrillator Sync Connector Nurse Call Connector RS232 Connector HDMI Connector 1 USB Connector	Network interface: RJ-45 Mains input Module bus Connector Defibrillator Sync Connector Nurse call Connector RS232 Connector HDMI Connector 1 USB connector (B105P/B125P) **3 USB Connector (B105M/B125M/B155M)**	**Equivalent to predicate**. Same Peripheral Interfaces remained for the proposed monitors B105P/B125P. 2 more USB connectors are added in the proposed monitors (B105M/B125M/B155M) to meet different customer needs. The functionality of the 2 new added USB connectors is the same as the existing USB connector. The changes do not significantly affect substantial equivalence.
• Alarm Classification	Four levels - high, medium, low and information	Four levels - high, medium, low and information	**Identical**
• Alarm Notification	Audible and visual	Audible and visual	**Identical**
• Alarm Setting	Default and individual	Default and individual	**Identical**
• Audio pause	audible pause alarms for 2 min	audible pause alarms for 2 min	**Identical**
• Audio pause method	Audio pause key by Software	Audio pause key by Software **Gesture control (Not applicable for B105M/B105P)**	**Equivalent to predicate**. Additional audio pause method by gesture for bigger screen models (B125M /P and B155M) to reduce unnecessary touch and better support cleaning and disinfecting the device in clinical environment. The changes do not significantly affect substantial equivalence.
• Alarm Volume Adjustment	Yes Single setting for High/Medium/Low priority alarms	Yes One setting for High/Medium priority alarms. **One setting for low priority alarms.**	**Equivalent to predicate**. Separated low priority alarm volume adjustment setting form High/Medium priority alarm setting. This change maintains the same range of alarm volume adjustment, while offering users greater flexibility to customize the volume levels based on the urgency of the alarms. The changes do not significantly affect substantial equivalence.

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• Alarm Tone for low priority alarm	Repeat	Repeat, **Single**	**Equivalent to predicate**. The proposed device provided additional option to set the low priority alarm tone to “single” alarm. Low priority alarms are the non-critical alarms, the “single” tone alarm provides the flexibility to allow clinician to focus more on critical alarms (high/medium priority alarms) by reducing the alarm sound fatigue caused by low priority non-critical alarms. The changes do not significantly affect substantial equivalence.
• Alarm light brightness	Fixed	**Adjustment**	**Equivalent to predicate**. The proposed monitors support the alarm light brightness adjustment to provide patient more comfortable environment. The brightness adjust is password protected, the clinicians can configure bright range per clinical environment with password. The changes do not significantly affect substantial equivalence.
• Connection with GE HealthCare anesthesia device	Not support	**Support**	The proposed monitor provided connection capability to receive additional patient monitoring data (Respiratory Gas, Spirometry) from GE HealthCare anesthesia devices through device serial interface for displaying, storing and printing the monitoring data on monitor. The related monitoring data communication flow is unidirectional only from Anesthesia devices to the proposed monitors. It is important to note that this data connection does not affect any of anesthesia or monitoring functionality of anesthesia device connected with the proposed monitor. The changes do not significantly affect substantial equivalence.

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• Early Warning Score Calculate Parameters	NEWS (National Early Warning Score) - Temperature - Respiration rate - Oxygen saturation - Pulse rate - Systolic blood pressure - Level of Consciousness - Air or oxygen - Hypercapnic Respiratory Failure	NEWS: (National Early Warning Score) - Temperature - Respiration rate - Oxygen saturation - Pulse rate - Systolic blood pressure - Level of Consciousness - Air or oxygen - Hypercapnic Respiratory Failure **MEWS:(Modified Early warning score)** - Temperature - Respiration rate - Pulse rate - Systolic blood pressure - Level of Consciousness - **Hourly Urine for 2 hours**	**Equivalent to predicate**. The proposed device supports additional MEWS protocol for early warning score calculation which involve additional parameter calculation for Hourly Urine for 2 hours (hourly urine for 2 hours is entered by the clinical user after observing the patient's physical condition, not the monitor measurement parameter.) The MEWS with different set of parameters for Early Warning Score calculation follows the same principle as existing NEWS. The changes do not significantly affect substantial equivalence.
• Operating System	Linux (Rev 4.19.141)	Linux **(Rev 6.1.53)**	**Equivalent to predicate**. The two versions of the Operation System use the same technology. Continuous Linux development, the updated version of Linux allows better technical support and cybersecurity while maintaining the same functionality, operation and performance. The changes do not significantly affect substantial equivalence.
• Display size	B105P/B105M: 10.1-inch B125P/B125M: 12.1-inch B155M: 15.6-inch	B105P/B105M: 10.1-inch B125P/B125M: 12.1-inch B155M: 15.6-inch	**Identical**
• Networking Interface	LAN WLAN	LAN WLAN	**Identical**
• Networking Protocol	CARESCAPE protocol HL7 NTP	CARESCAPE protocol HL7 / **HL7 Secured** NTP / **NTP Secured (NTS)**	**Equivalent to predicate**. The proposed devices support the same networking protocols as the predicate devices but additional providing the encryption for HL7 and NTP for continuous improvements in cybersecurity. The changes do not significantly affect substantial equivalence.
• Medical Standards	Safety and EMC: IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-1-8:2012	Safety and EMC: IEC 60601-1:2005+ A1:2012+ **A2:2020** IEC 60601-1-2:**2020** IEC 60601-1-8: **2020**	**Equivalent to predicate**. Newer updated versions of standards were used for the following standards:

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	ANSI/AAMI EC57: 2012 IEC 60601-2-26: 2019 IEC60601-2-27: 2011+ C1:2012 IEC 80601-2-30:2018 IEC 60601-2-34:2011 IEC 60601-2-40:2016 IEC 80601-2-49:2018 ISO 80601-2-56:2017+A1:2018 ISO 80601-2-61: 2017+C1:2018 IEC 62304:2006+A1:2015 IEC 60601-1-6: 2010+A1:2013 IEC 62366-1:2015 ISO 14971:2019 Environment & Package: IEC 60068:2 series Environmental testing including with IEC 60068-2-6, Test Fc (2007-12 IEC 60068-2-64, Test Fh (2008) / AMD1/2019. IEC 60068-2-27, Test Ea (2008-02). IEC 60068-2-31, Test Ec (2008-05). ISTA 2A:2011 Labeling: ISO 20417:2021 ISO 15223-1:2021 ISO 17664:2017 RFID: AIM 7351731:2017 Battery: UL 2054:2004 IEC 62133-2:2017 UL 1642:2012 Wireless: IEEE ANSI C63.27-2017	ANSI/AAMI EC57: 2012 IEC 60601-2-26:2019/**COR1:2021** IEC 60601-2-27: 2011+C1:2012 IEC 80601-2-30: 2018 IEC 60601-2-34: 2011 IEC 60601-2-40:2016 IEC 80601-2-49:2018 ISO 80601-2-56:2017+A1:2018 ISO 80601-2-61: 2017+C1:2018 IEC 62304:2006+A1:2015 IEC 60601-1-6: **2020** IEC 62366-1: **2020** ISO 14971:2019 **IEC TR 60601-4-2:2016** Environment & Package: IEC 60068:2 series Environmental testing including with IEC 60068-2-6, Test Fc (2007-12 IEC 60068-2-64, Test Fh (2008) / AMD1/2019. IEC 60068-2-27, Test Ea (2008-02). IEC 60068-2-31, Test Ec (2008-05). ISTA 2A:2011 Labeling: ISO 20417: 2021 ISO 15223-1: 2021 **ISO 17664-2:2021** Battery: UL 2054:2004 IEC 62133-2:2017/**AMD1:2021** UL 1642:2012 Wireless: IEEE ANSI C63.27-2021	• IEC 60601-1:2005+ A1:2012+ A2:2020 • IEC 60601-1-2: 2020 • IEC 60601-1-8: 2020 • IEC 60601-2-26:2019/COR1:2021 • IEC 60601-1-6: 2020 • IEC 62366-1: 2020 • IEC 62133-2:2017/AMD1:2021 IEC TR 60601-4-2: 2016 are new tested standard to align with the requirement of FDA guidance on EMC issued on June 6, 2022. The ISO 17664:2017 standard was dropped since relevant content for the proposed device are covered by the newer ISO 17664-2: 2021. Similarly, the RFID standard AIM 7351731:2017 was removed since the new version IEC6060-1-2:2020 now takes the same testing into accountant. Updating to newer standard versions or new introduced above standards does not significant affect substantial equivalence.
• Hard keys	Trim Knob and power key	Power key	**Equivalent to predicate**. Trim Knob was removed in the proposed device for better supporting cleaning and disinfecting the device in clinical environment. Touch screen is the primary way to operate the device and provides the access to all the functionalities. Trim knob serves as an alternative way to operate the device in a traditional way. The proposed monitors continue to provide all the required device operations through the same type of touch screen as the predicate monitors.

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			The changes do not significantly affect substantial equivalence.
• Printers Supported	Local Thermal Array Recorder Remote Laser Printer via central station Remote Thermal Recorder via central station	Local Thermal Array Recorder Remote Laser Printer via central station Remote Thermal Recorder via central station **Network laser printer**	**Equivalent to predicate**. Additional support network laser printer to pint the patient data per customer needs The network laser printing utilizes specialized IPPS protocol that allows for the additional printing of images in addition to Numeric data and waveform which currently supported in remote printing. The changes do not significantly affect substantial equivalence.
• Battery	Lithium Ion	Lithium Ion	**Identical**
• Battery model	Basic battery High capacity battery	Basic battery High capacity battery	**Identical**
• Storage temperature	– 20°C to 60°C	– 20°C to 60°C	**Identical**
• Storage humidity	10 to 90%. Non-condensing	10 to 90%. Non-condensing	**Identical**
• Storage atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa	**Identical**
• Power supply	From AC, internal battery	From AC, internal battery	**Identical**
• Power Requirements	100 - 240 V ±10%, 50 /60 Hz	100 - 240 V ±10%, 50 /60 Hz	**Identical**
• Host Operating temperature	-Normal operation: 5 to 40°C -While charging batteries: 5 to 35°C	-Normal operation: 5 to 40°C -While charging batteries: 5 to 35°C	**Identical**
• Power Consumption	<=150 VA	<=150 VA	**Identical**
• Protection	Class II	Class II	**Identical**
• Operating humidity range	15 to 90%. Non-condensing	15 to 90%. Non-condensing	**Identical**
• Operating atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)	700 to 1060 hPa (525 to 795 mmHg)	**Identical**
• Height	B105P, B105M: 275±5mm B125P, B125M: 280±5mm B155M: 305±5mm	B105P, B105M: 275±5mm B125P, B125M: 280±5mm B155M: 305±5mm	**Identical**
• Width	B105P, B105M: 265±5mm B125P, B125M: 312±5mm B155M: 405±5mm	B105P, B105M: 265±5mm B125P, B125M: 312±5mm B155M: 405±5mm	**Identical**
• Depth	B105P, B105M: 175±5mm B125P, B125M: 175±5mm B155M: 175±5mm	B105P, B105M: 175±5mm B125P, B125M: 175±5mm B155M: 175±5mm	**Identical**

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• Weight	B105P, B105M:3.8 Kg B125P, B125M:4.2 Kg B155M:5.2 Kg	B105P,B105M:3.8 Kg B125P,B125M:4.2 Kg B155M:**5.5 Kg**	**Equivalent to predicate**. The proposed device B155M enlarge front panel size to suit the trim knob removal which increased the weight of the device slightly. The changes do not significantly affect substantial equivalence.

Determination of Substantial Equivalence (807.92(b)(1):

Summary of Non-Clinical Tests:

Bench testing related to software, hardware and performance including applicable consensus standards was conducted on the proposed monitors B105M/B125M/B155M/B105P/B125P demonstrate that the design meets the specifications.

Per the FDA guidance titled "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff, Document issued on December 20, 2019", the following was verified:

- Hardware Bench Testing
- Alarms Bench Testing
- IEC 80601-2-26:2019/COR1:2021
- IEC 60601-2-27:2011+C1: 2012
- IEC 80601-2-30: 2018
- IEC 60601-2-34: 2011
- IEC 60601-2-40:2016
- IEC 80601-2-49:2018
- ISO 80601-2-55:2018
- ISO 80601-2-56:2017+A1:2018
- ISO 80601-2-61: 2017+ C1:2018
- ANSI/AAMI EC57:2012

The proposed monitors B105M/B125M/B155M/B105P/B125P meet the EMC requirements described in IEC 60601-1-2:2014+A1:2020 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -

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Collateral Standard: Electromagnetic disturbances - Requirements and tests".

Compliance according to the “Electromagnetic Compatibility (EMC) of Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on June 6, 2022.”

The proposed monitors B105M/B125M/B155M/B105P/B125P passed the testing for IEC TR 60601-4-2:2016 "Medical electrical equipment -Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

The proposed monitor B105M/B125M/B155M/B105P/B125P also passed 5G cellular immunity testing per ANSI C63.18-2014 “American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters”.

The proposed monitors B105M/B125M/B155M/B105P/B125P have been evaluated for electromagnetic compatibility and potential risks from common emitters in the user environment.

The proposed monitors B105M/B125M/B155M/B105P/B125P meet the electrical safety requirements of IEC 60601-1:2005+A1:2012+A2:2020 " Medical electrical equipment – Part 1: General requirements for basic safety and essential performance". This testing was performed by a recognized independent and Certified Body Testing Laboratory (CBTL) under the IECEE CB Scheme.

Additional data is provided for compliance to:

- IEC 60601-1-8:2006+A1:2012+A2:2020: Medical electrical equipment - part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 80601-2-26:2019/COR1:2021： Medical electrical equipment - Part 2-26: Particular requirements for the

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basic safety and essential performance of electroencephalographs

- IEC 60601-2-27:2011+C1: 2012: Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30:2018: Medical electrical equipment Part 2-30: Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34: 2011: Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
- IEC 60601-2-40:2016: Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment - Edition 2.0
- IEC 80601-2-49:2018: Medical electrical equipment Part 2-49: Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55:2018: Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56:2017+A1:2018: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 80601-2-61:2017+C1:2018: Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Environmental (Mechanical, and Thermal Safety) testing, based on the proposed monitors B105M/B125M/B155M/B105P/B125P uses and locations, was confirmed to meet the specifications listed in the requirements. The proposed monitors B105M/ B125M/B155M/B105P/B125P specifications verification evidence is included for the following:

- Operating temperature

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- Operating humidity
- Operating pressure
- Storage and transport temperature
- Storage and transport humidity
- Storage and transport pressure
- Mechanical stress
- Fluid ingress
- Packaging Bench Testing

The proposed monitors B105M/B125M/B155M/B105P/B125P follow the guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. Document issued on March 17, 2015 (Appendix E of this guidance was updated on June 9, 2017)". Reprocessing efficacy validation has been conducted in accordance with the documented reprocessing instructions using worst-case devices/components of the proposed monitors B105M/B125M/B155M/B105P/B125P. The reprocessing efficacy validation met the acceptance criteria for the reprocessing efficacy validation tests.

The proposed monitors B105M/B125M/B155M/B105P/B125P follow the "Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on: February 3, 2016, and the following standards:

- IEC 60601-1-6:2010+A1:2013+A2:2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1:2015+A1:2020: Medical devices - Part 1: Application of usability engineering to medical devices

Summative Usability testing has been conducted with 16 US Clinical users. The usability testing of the proposed monitors B105M/B125M/B155M/B105P/B125P follow the FDA Guidance for Industry and Food and Drug Administration Staff "Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on: February 3, 2016".

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Wireless performance data was provided related to:

- EMC testing per IEC 60601-1-2:2020, including electromagnetic immunity in the exclusion band and proximity fields from RF wireless communication.
- FDA Guidance-Radio Frequency Wireless Technology in Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on: August 14, 2013
- IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence.

The proposed monitors B105M/B125M/B155M/B105P/B125P follows the FDA software guidance documents as outlined in this submission.

- Content of Premarket Submissions for Device Software Functions. Guidance for Industry and Food and Drug Administration Staff. Document issued on June 14, 2023
- General Principles of Software Validation. Final Guidance for Industry and FDA Staff. Document issued on: January 11, 2002
- Off-The-Shelf Software Use in Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on August 11, 2023
- Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on January 14, 2005
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Guidance for Industry and Food and Drug Administration Staff. Document issued on September 27,2023
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Document issued on September 6, 2017

Software testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions. Guidance for Industry and Food and Drug Administration Staff. Document issued on June 14, 2023." Based on the risk level of the proposed monitors B105M/ B125M/B155M/B105P/B125P, the document level for this

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submission is considered as "Enhanced" documentation level. Software standard IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes and risk management standard ISO 14971:2019 Medical devices - Application of risk management to medical devices were also applied to the design.

Patient safety, security, and privacy risks have been addressed in the design and development of the proposed monitors B105M/ B125M/B155M/B105P/B125P including a Security Risk Assessment, Threat model and Penetration testing. This includes system integrity controls, access controls, audit controls, network controls which address the General Principles and Security Capabilities outlined in the "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Guidance for Industry and Food and Drug Administration Staff. Document issued on September 27, 2023."

Clinical (807.92(b)(2)): Summary of Clinical Tests:

The subject of this premarket submission, the proposed monitors B105M/B125M/B155M/B105P/B125P did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)): GE HealthCare considers the proposed monitors B105M/B125M/B155M/B105P/B125P to be substantially equivalent to the predicate devices.